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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/804,576
				Filing Date	3/19/2004
Date Submitted: December 27, 2007				First Named Inventor	Fred H. MILLER
				Art Unit	1609
(use as many sheets as necessary)				Examiner Name	Aradhana Sasan
				Attorney Docket Number	027668-0108
Sheet	1	of	1		

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Application Document Serial Number-Kind Code ² (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
/A.S./	C1	WO 01/03676	01/18/2001	BioProgress Technology Int'l Inc.		
/A.S./	C2	WO 00/28976	05/25/2000	A.B. Technologies, LLC		
/A.S./	C3	EP 0211079	02/25/1987	Fujisawa Pharmaceutical Co., Ltd.		
/A.S./	C4	UK 2353950	03/14/2001	BioProgress Technology Int'l Inc.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
/A.S./	C5	"Formulation Advantages: The hard gelatin capsule is a versatile container," The Hard Gelatin Capsule Advantage, BAS179-E-96, 1996, 3 pages.	
/A.S./	C6	"Producto de llenado de las capsulas," Todo sobre la capsula de gelatina dura, BAS126SP 1997, Capsugel Library, pp. 26-27 (4 pages).	
/A.S./	C7	"Fill material for hard gelatin capsules," All about the hard gelatin capsule, BAS126E 1999, Capsugel Library, pp. 26-27 (4 pages).	

Examiner Signature	/Aradhana Sasan/	Date Considered	01/08/2008
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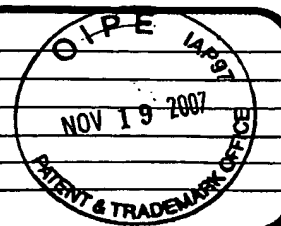
Date Submitted: June 13, 2007

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Sheet 1 of 5

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		Number-Kind Code ² (if known)			
/A.S./	A1	3,072,528	01-08-1963	KLUDAS et al.	
	A2	4,578,075	03-25-1986	URQUHART et al.	
	A3	4,606,909	08-19-1986	BECHGAARD et al.	
	A4	4,627,808	12-09-1986	HUGHES	
	A5	4,642,233	02-10-1987	URQUHART et al.	
	A6	4,681,583	07-21-1987	URQUHART et al.	
	A7	4,695,466	09-22-1987	MORISHITA et al.	
	A8	4,764,359	08-16-1988	LEMELSON	
	A9	4,702,732	10-27-1987	POWERS et al.	
	A10	4,773,907	09-27-1988	URQUHART et al.	
	A11	4,793,493	12-27-1988	MAKIEJ	
	A12	4,822,619	04-18-1989	EICHEL et al.	
	A13	4,863,741	09-05-1989	BECKER	
	A14	4,904,476	02-27-1990	MEHTA et al.	
	A15	4,936,461	06-26-1990	MAKIEJ	
	A16	4,994,279	02-19-1991	AOKI et al.	
	A17	5,017,379	05-21-1991	LEMELSON	
	A18	5,196,205	03-23-1993	BORODY	
	A19	5,256,684	10-26-1993	MARSHALL	
	A20	5,310,555	05-10-1994	ZIMMER	
	A21	5,314,696	05-24-1994	PAULOS	
	A22	5,394,980	03-07-1995	TSAI	
	A23	5,472,695	12-05-1995	NEEMAN et al.	
	A24	5,472,708	12-05-1995	CHEN	
	A25	5,501,857	03-26-1996	ZIMMER	
/A.S./	A26	5,558,878	09-24-1996	PAULOS	

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U.S. PATENT DOCUMENTS

		Document Number			
/A.S./	A27	5,560,912	10-01-1996	NEEMAN et al.	
	A28	5,562,918	10-08-1996	STIMPSON	
	A29	5,576,019	11-19-1996	PAULOS	
	A30	5,582,837	12-10-1996	SHELL	
	A31	5,587,837	12-24-1996	KEBO	
	A32	5,672,359	09-30-1997	DIGENIS et al.	
	A33	5,674,858	10-07-1997	McCOLM	
	A34	6,024,980	02-15-2000	HOY	
	A35	6,262,092	07-17-2001	CHANG et al.	
	A36	6,350,468 B1	02-26-2002	SANSO	
	A37	6,352,719	03-05-2002	BROWN et al.	
	A38	6,455,574	09-24-2002	BUCH	
	A39	6,486,182	11-26-2002	CHANG et al.	
	A40	6,517,866 B1	02-11-2003	AM ENDE et al.	
	A41	6,569,152 B2	05-27-2003	BRINES et al.	
	A42	6,620,806	09-16-2003	DAY et al.	
	A43	6,737,145	05-18-2004	WATANABE et al.	
	A44	US 2002/0081333 A1	06-27-2002	OSHLACK et al.	
	A45	US 2002/0094992 A1	07-18-2002	MacLEAN	
	A46	US 2002/0192277 A1	12-19-2002	OSHLACK et al.	
	A47	US 2003/0035839 A1	02-20-2003	HIRSH et al.	
	A48	US 2003/0068369 A1	04-10-2003	McALLISTER et al.	
	A49	US 2003/0194428 A1	10-16-2003	MILLER et al.	
	A50	US 2003/0194429 A1	10-16-2003	MILLER et al.	
↓	A51	US 2003/0194430 A1	10-16-2003	MILLER et al.	
	A52	US 2003/0194431 A1	10-16-2003	MILLER et al.	
/A.S./	A53	US 2005/0008690 A1	01-13-2005	MILLER	

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Examiner Name	Aradhana Sasan
Attorney Docket Number	027668-0108

U.S. PATENT DOCUMENTS

		Document Number		
/A.S./	A54	5 074 426	12-24-1991	Goodhart et al.
/A.S./	A55	5 674 530	10-07-1997	AMIDON et al.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
/A.S./	A56	DE 27 29 068 A1	01-11-1979	Liedtke		
/A.S./	A57	EP 0141373 A2	05-15-1985	Plant Genetics, Inc.		
/A.S./	A58	EP 0228067 A2	07-08-1987	Taisho Pharmaceutical Co.		
	A59	EP 0284847 A1	09-20-1988	Zambon Group S.p.A.	N/A (AS) 12/10/07	
/A.S./	A60	EP 0319318 A2	06-07-1989	McNeil Consumer Products Company		
	A61	EP 0325571 A1	07-26-1989	KabiVitrum AB		
	A62	FR 1454013	09-30-1966	PLURIPHARM		
	A63	FR 2524311	04-05-1982	Azalbert Gilles		
	A64	GB 2103564 A	02-23-1983	Canadian Minister of National Defence		
	A65	GB 2365336 A	02-20-2002	MW Encap Limited		
	A66	JP 60-193917	02-10-1985			
	A67	WO 01/32217 A2	05-10-2001	Depomed, Inc.		
	A68	WO 02/060384 A2	08-08-2002	Smithkline Beecham PLC.		
	A69	WO 02/060385 A2	08-08-2002	Smithkline Beecham PLC.		
	A70	WO 02/07710 A2	01-31-2002	NW Encap Limited		
↓	A71	WO 02/11544 A1	02-14-2002	Encapsulation Systems, Inc.		
	A72	WO 85/00015	01-03-1985	Pharmacia AB		
/A.S./	A73	WO 89/03219	04-20-1989	BORODY, Thomas, Julius		

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/A.S./	A74	WO 90/11129	10-04-1990	Nehézvegyipari Kutató Intézet		
	A75	WO 92/11848	07-23-1992	The Procter & Gamble Company		
	A76	WO 93/00439	01-07-1993	Brown University Research Foundation		
	A77	WO 94/23770	10-27-1994	Leiras OY		
	A78	WO 95/10262	04-20-1995	R.P. Scherer Corporation		
	A79	WO 96/02236	02-01-1996	MOORE, Trevor		
	A80	WO 96/10996	04-18-1996	The University of Kentucky Research Foundation		
	A81	WO 99/30693	06-24-1999	Axcan Pharma Inc.		
	A82	WO 99/59413	11-25-1999	Shanghai Sine Pharmaceutical Corp., LTD.		
	A83	WO 95/16438	06-22-1995	Cortects Limited		
/A.S./	A84	WO 92/06680	04-30-1992	Cortects Limited		

NON PATENT LITERATURE DOCUMENTS

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	A85	"Pifizer's Gadeet approved in the US The FDA has approved Pfizer's Gadeet in the US," DATAMONITOR COMMENTWIRE, February 4, 2004, 1 PG. N/A (AS) 12/10/07	
/A.S./	A86	"The Hard Gelatin Capsule Advantage," Innercap Technologies Inc., 2004, pp. 2-9.	
/A.S./	A87	Michael HOPKIN, "A healthy heart in a single pill," Nature News Service, Macmillan Magazines Ltd, June 27, 2003, pp. 1 & 2.	
/A.S./	A88	Alexis BORISY, et al., "Systematic discovery of multicomponent therapeutics," PNAS, Vol. 100, No. 9, June 24, 2003, pp. 7977-7982.	
/A.S./	A89	Drug Delivery Technology, 2005, vol. 5, no. 9, pp. 40-86.	

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	A90	"Cominex Dual Drug, Dual Release," Drug Delivery Technologies Cominex Pharmaceut Co., 2003, 1 pg			N/A (AS) 12/10/07
	A91	"Layer Capsules ENCAP DRUG DELIVERY," layer capsules to administer solid liquid components, 2003, 1 PG.			N/A (AS) 12/10/07
/A.S./	A92	"Main Benefits of Liquid Fill ENCAP DRUG DELIVERY" liquid fill encapsulation beats tablet alternative, http://www.encapdrugdelivery.com/benefits.html , 2003, 1 PG.			
	A93	"DuoCap Capsules," ENCAP DRUG DELIVERY liquid fill encapsulation preferable to tablet alternative, http://www.encapdrugdelivery.com/multi-component.html, 2003. PGS. 1 & 2.			N/A (AS) 12/10/07
	A94	"What does encaps do? ENCAP DRUG DELIVERY" pharmaceutical companies prefer liquid fill capsule solutions, http://www.encapdrugdelivery.com/, 2003, 1 PG.			N/A (AS) 12/10/07
	A95	"Ingestible Encapsulation," BioProgress Ingestible Encapsulation, http://www.bioprogress.com/ingestible.html, 2003 pp. 1-2.			N/A (AS) 12/10/07
/A.S./	A96	Scott HENSLEY, "Drug Makers 'Combos' Treat Two Disorders With One Pill," The Wall Street Journal, 2004, (Copyright © 2004, Dow Jones & Company, Inc.), pp. 1-3.			
/A.S./	A97	"FDA Approves Pfizer Medicine Caduet for the Treatment of Hypertension and High Cholesterol," FDA Approves Pfizer Medicine Caduet for the Treatment of Hypertension and High Cholesterol, http://www.medicalnewstoday.com/medicalnews.php?newsid=5666 , February 3, 2004, pp. 1-3.			

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	A3	4,608,909	08-19-1986	BECHGAARD et al.	
	A4	4,827,808	12-09-1986	HUGHES	
	A5	4,842,233	02-10-1987	URQUHART et al.	
	A6	4,681,583	07-21-1987	URQUHART et al.	
	A7	4,695,466	08-22-1987	MORISHITA et al.	
	A8	4,764,359	08-16-1988	LEMELSON	
	A9	4,702,732	10-27-1987	POWERS et al.	
	A10	4,773,907	09-27-1988	URQUHART et al.	
	A11	4,793,493	12-27-1988	MAKIEJ	
	A12	4,822,619	04-18-1989	EICHEL et al.	
	A13	4,863,741	09-05-1989	BECKER	
	A14	4,904,476	02-27-1990	MEHTA et al.	
	A15	4,938,461	08-26-1990	MAKIEJ	
	A16	4,994,279	02-19-1991	AOKI et al.	
	A17	5,017,379	05-21-1991	LEMELSON	
	A18	5,198,205	03-23-1993	BORODY	
	A19	5,250,684	10-26-1993	MARSHALL	
	A20	5,310,555	05-10-1994	ZIMMER	
	A21	5,314,696	05-24-1994	PAULOS	
	A22	5,394,980	03-07-1995	TSAI	
	A23	5,472,695	12-05-1995	NEEMAN et al.	
	A24	5,472,708	12-05-1995	CHEN	
	A25	5,501,857	03-28-1996	ZIMMER	
/A.S./	A26	5,558,878	09-24-1996	PAULOS	

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PAGE 9/9 * RCVD AT 9/20/2007 12:56:23 PM [Eastern Daylight Time] * SVR:USPTO-EFXXF-2/9 * DNIS:2739022 * CSID: * DURATION (mm-ss):03-20

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		Filing Date	03/19/2004
Date Submitted: June 13, 2007 (use as many sheets as necessary)		First Named Inventor	Fred H. MILLER
		Art Unit	1809
Sheet 2 of 5		Examiner Name	Aradhana Sasan
		Attorney Docket Number	027668-0108

U.S. PATENT DOCUMENTS				
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/A.S./	A27	5,560,912	10-01-1996	NEEMAN et al.
	A28	5,562,918	10-08-1996	STIMPSON
	A29	5,576,019	11-19-1996	PAULOS
	A30	5,582,837	12-10-1996	SHELL
	A31	5,587,837	12-24-1996	KEBO
	A32	5,672,359	09-30-1997	DIGENIS et al.
	A33	5,674,858	10-07-1997	McCOLM
	A34	6,024,980	02-15-2000	HOY
	A35	6,262,092	07-17-2001	CHANG et al.
	A36	6,350,488 B1	02-28-2002	SANSO
	A37	6,352,719	03-05-2002	BROWN et al.
	A38	6,455,574	09-24-2002	BUCH
	A39	6,486,182	11-26-2002	CHANG et al.
	A40	6,517,866 B1	02-11-2003	AM ENDE et al.
	A41	6,569,152 B2	05-27-2003	BRINES et al.
	A42	6,620,806	09-16-2003	DAY et al.
	A43	6,737,145	05-18-2004	WATANABE et al.
	A44	US 2002/0081333 A1	06-27-2002	OSHLACK et al.
	A45	US 2002/0094992 A1	07-18-2002	MacLEAN
	A46	US 2002/0192277 A1	12-19-2002	OSHLACK et al.
	A47	US 2003/0035839 A1	02-20-2003	HIRSH et al.
	A48	US 2003/0068369 A1	04-10-2003	McALLISTER et al.
	A49	US 2003/0194428 A1	10-16-2003	MILLER et al.
	A50	US 2003/0194429 A1	10-16-2003	MILLER et al.
✓	A51	US 2003/0194430 A1	10-16-2003	MILLER et al.
	A52	US 2003/0194431 A1	10-16-2003	MILLER et al.
/A.S./	A53	US 2005/0008690 A1	01-13-2005	MILLER

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		Art Unit	1609
Sheet 3 of 5		Examiner Name	Aradhana Sasan
		Attorney Docket Number	027688-0108

U.S. PATENT DOCUMENTS				
		Document Number		
/A.S./	A54	5 074 426	12-24-1991	Goodhart et al.
/A.S./	A55	5 674 530	10-07-1997	AMIDON et al.

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code* Number* Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*
/A.S./	A56	DE 27 29 068 A1	01-11-1979	Liedtke	Abstract only (AS) 12/10/07	
/A.S./	A57	EP 0141373 A2	05-15-1985	Plant Genetics, Inc.		
/A.S./	A58	EP 0228067 A2	07-08-1987	Taiho Pharmaceutical Co.		
	A59	EP 0284017 A1	08-28-1988	Zambon Group S.p.A.	N/A (AS) 12/10/07	
/A.S./	A60	EP 0319318 A2	06-07-1989	McNeil Consumer Products Company		
	A61	EP 0325571 A1	07-26-1989	KabiVitrum AB		
	A62	FR 1454013	09-30-1966	PLURIPHARM		
	A63	FR 2524311	04-05-1982	Azalbert Gilles		
	A64	GB 2103564 A	02-23-1983	Canadian Minister of National Defence		1
	A65	GB 2365336 A	02-20-2002	MW Encap Limited		
	A66	JP 60-193917	02-10-1985			
	A67	WO 01/32217 A2	05-10-2001	Depomed, Inc.		
	A68	WO 02/060384 A2	08-08-2002	Smithkline Beecham PLC.		
	A69	WO 02/060385 A2	08-08-2002	Smithkline Beecham PLC.		
	A70	WO 02/07710 A2	01-31-2002	NW Encap Limited		
✓	A71	WO 02/11544 A1	02-14-2002	Encapsulation Systems, Inc.		
	A72	WO 85/00015	01-03-1985	Pharmacia AB		
/A.S./	A73	WO 89/03219	04-20-1989	BORODY, Thomas, Julius		

Examiner Signature	/Aradhana Sasan/	Date Considered	12/10/2007
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				Art Unit	1809
Sheet 4 of 5				Examiner Name	Aradhana Sasan
				Attorney Docket Number	027668-0108

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/A.S./	A74	WO 90/11129	10-04-1990	Nehézvegyipari Kutató Intézet		
	A75	WO 92/11848	07-23-1992	The Procter & Gamble Company		
	A76	WO 93/00439	01-07-1993	Brown University Research Foundation		
	A77	WO 94/23770	10-27-1994	Leiras OY		
	A78	WO 95/10282	04-20-1995	R.P. Scherer Corporation		
	A79	WO 96/02236	02-01-1996	MOORE, Trevor		
	A80	WO 96/10996	04-18-1996	The University of Kentucky Research Foundation		
	A81	WO 99/30693	06-24-1999	Axcan Pharma Inc.		
	A82	WO 99/59413	11-25-1999	Shanghai Sine Pharmaceutical Corp., LTD.		
	A83	WO 95/16438	06-22-1995	Cortecs Limited		
/A.S./	A84	WO 92/06880	04-30-1992	Cortecs Limited		

NON PATENT LITERATURE DOCUMENTS			
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	A85	"Pfizer Caduet approved in US The FDA has approved Pfizer's Caduet in the US." DATAMONITOR COMMENTWIRE, February 4, 2004, 1 PG.	N/A
/A.S./	A86	"The Hard Gelatin Capsule Advantage," Innercap Technologies Inc., 2004, pp. 2-9.	
/A.S./	A87	Michael HOPKIN, "A healthy heart in a single pill," Nature News Service. Macmillan Magazines Ltd, June 27, 2003, pp. 1 & 2.	
/A.S./	A88	Alexis BORISY, et al., "Systematic discovery of multicomponent therapeutics," PNAS, Vol. 100, No. 9, June 24, 2003, pp. 7977-7982.	
/A.S./	A89	Drug Delivery Technology, 2005, vol. 5, no. 9, pp. 40-88.	

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Date Submitted: June 13, 2007 (use as many sheets as necessary)		First Named Inventor	FRED H. MILLER
		Art Unit	1809
Sheet 5 of 5		Examiner Name	Aradhana Sasan
		Attorney Docket Number	027668-0108

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T#
	A90	"Geminox - Dual Drugs, Dual Releases," Drug-Delivery Technologies - Geminox - Penwest Pharmaceutical Co., 2003, 1 pg	N/A (A) 12/10/07
	A91	"Layer-Capsules ENCAP DRUG DELIVERY," layer capsules co-administer solid liquid components, 2003, 1 PG.	N/A (A) 12/10/07
I.A.S./	A92	"Main Benefits of Liquid Fill ENCAP DRUG DELIVERY" liquid fill encapsulation beats tablet alternative, http://www.encapdrugdelivery.com/benefits.html , 2003, 1 PG.	
	A93	"DuoCap Capsules™ ENCAP DRUG DELIVERY" liquid fill encapsulation preferable to tablet alternative, http://www.encapdrugdelivery.com/multi-component.html , 2003, PGS. 1 & 2.	N/A (A) 12/10/07
	A94	"What does encap do? ENCAP DRUG DELIVERY" pharmaceutical companies prefer liquid fill capsule solutions, http://www.encapdrugdelivery.com/ , 2003, 1 PG.	N/A (A) 12/10/07
	A95	"Ingestible Encapsulation," BioProgress - Ingestible Encapsulation, http://www.bioprogress.com/ingestible.html , 2003 pp. 1-2.	N/A (A) 12/10/07
I.A.S./	A96	Scott HENSLEY, "Drug Makers 'Combos' Treat Two Disorders With One Pill," The Wall Street Journal, 2004, (Copyright © 2004, Dow Jones & Company, Inc.), pp. 1-3.	
I.A.S./	A97	"FDA Approves Pfizer Medicine Caduet for the Treatment of Hypertension and High Cholesterol," FDA Approves Pfizer Medicine Caduet for the Treatment of Hypertension and High Cholesterol, http://www.medicalnewstoday.com/medicalnews.php?newsId=5666 , February 3, 2004, pp. 1-3.	

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	A5	4,642,233	02-10-1987	URQUHART et al.	
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	A19	5,258,684	10-26-1993	MARSHALL	
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	A21	5,314,696	05-24-1994	PAULOS	
	A22	5,394,980	03-07-1995	TSAI	
	A23	5,472,695	12-05-1995	NEEMAN et al.	
	A24	5,472,708	12-05-1995	CHEN	
	A25	5,501,857	03-26-1996	ZIMMER	
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		Document Number		
/A.S./	A27	5,560,912	10-01-1996	NEEMAN et al.
	A28	5,562,918	10-08-1996	STIMPSON
	A29	5,576,019	11-19-1996	PAULOS
	A30	5,582,837	12-10-1996	SHELL
	A31	5,587,837	12-24-1996	KEBO
	A32	5,672,359	09-30-1997	DIGENIS et al.
	A33	5,674,858	10-07-1997	McCOLM
	A34	6,024,980	02-15-2000	HOY
	A35	6,262,092	07-17-2001	CHANG et al.
	A36	6,350,468 B1	02-26-2002	SANSO
	A37	6,352,719	03-05-2002	BROWN et al.
	A38	6,455,574	09-24-2002	BUCH
	A39	6,486,182	11-26-2002	CHANG et al.
	A40	6,517,866 B1	02-11-2003	AM ENDE et al.
	A41	6,569,152 B2	05-27-2003	BRINES et al.
	A42	6,620,806	09-16-2003	DAY et al.
	A43	6,737,145	05-18-2004	WATANABE et al.
	A44	US 2002/0081333 A1	06-27-2002	OSHLACK et al.
	A45	US 2002/0094992 A1	07-18-2002	MacLEAN
	A46	US 2002/0192277 A1	12-19-2002	OSHLACK et al.
	A47	US 2003/0035839 A1	02-20-2003	HIRSH et al.
	A48	US 2003/0068369 A1	04-10-2003	McALLISTER et al.
	A49	US 2003/0194428 A1	10-16-2003	MILLER et al.
	A50	US 2003/0194429 A1	10-16-2003	MILLER et al.
	A51	US 2003/0194430 A1	10-16-2003	MILLER et al.
	A52	US 2003/0194431 A1	10-16-2003	MILLER et al.
/A.S./	A53	US 2005/0008690 A1	01-13-2005	MILLER

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/804,576
Date Submitted: June 13, 2007				Filing Date	03/19/2004
(use as many sheets as necessary)				First Named Inventor	Fred H. MILLER
Sheet 3 of 5				Art Unit	1609
				Examiner Name	Aradhana Sasan
				Attorney Docket Number	027668-0108

U.S. PATENT DOCUMENTS

		Document Number		
/A.S./	A54	5 074 426	12-24-1991	Goodhart et al.
/A.S./	A55	5 674 530	10-07-1997	AMIDON et al.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code* Number* Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
/A.S./	A56	DE 27 29 068 A1	01-11-1979	Liedtke		
/A.S./	A57	EP 0141373 A2	05-15-1985	Plant Genetics, Inc.		
/A.S./	A58	EP 0228067 A2	07-08-1987	Taisho Pharmaceutical Co.		
	A59	EP 0284017 A1	09-28-1988	Zambon Group S.p.A.	N/A (AS) 12/10/07	
/A.S./	A60	EP 0319318 A2	06-07-1989	McNeil Consumer Products Company		
	A61	EP 0325571 A1	07-26-1989	KabiVitrum AB		
	A62	FR 1454013	09-30-1966	PLURIPHARM		
	A63	FR 2524311	04-05-1982	Azalbert Gilles		
	A64	GB 2103564 A	02-23-1983	Canadian Minister of National Defence		
	A65	GB 2365336 A	02-20-2002	MW Encap Limited		
	A66	JP 60-193917	02-10-1985			
	A67	WO 01/32217 A2	05-10-2001	Depomed, Inc.		
	A68	WO 02/060384 A2	08-08-2002	Smithkline Beecham PLC.		
	A69	WO 02/060385 A2	08-08-2002	Smithkline Beecham PLC.		
	A70	WO 02/07710 A2	01-31-2002	NW Encap Limited		
	A71	WO 02/11544 A1	02-14-2002	Encapsulation Systems, Inc.		
	A72	WO 85/00015	01-03-1985	Pharmacia AB		
/A.S./	A73	WO 89/03219	04-20-1989	BORODY, Thomas, Julius		

Examiner Signature	/Aradhana Sasan/	Date Considered	12/10/2007
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/A.S./	A74	WO 90/11129	10-04-1990	Nehézvegyipari Kutató Intézet		
	A75	WO 92/11848	07-23-1992	The Procter & Gamble Company		
	A76	WO 93/00439	01-07-1993	Brown University Research Foundation		
	A77	WO 94/23770	10-27-1994	Leiras OY		
	A78	WO 95/10262	04-20-1995	R.P. Scherer Corporation		
	A79	WO 96/02236	02-01-1996	MOORE, Trevor		
	A80	WO 96/10996	04-18-1996	The University of Kentucky Research Foundation		
	A81	WO 99/30693	06-24-1999	Axcan Pharma Inc.		
	A82	WO 99/59413	11-25-1999	Shanghai Sine Pharmaceutical Corp., LTD.		
	A83	WO 95/16438	06-22-1995	Cortectis Limited		
/A.S./	A84	WO 92/06680	04-30-1992	Cortectis Limited		

NON PATENT LITERATURE DOCUMENTS			
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	A85	Pfizer Conduct approved in US The FDA has approved Pfizer's Conduct in the US, "DATAMONITOR COMMENTWIRE, February 4, 2004, 1 PG.	N/A
/A.S./	A86	"The Hard Gelatin Capsule Advantage," Innecap Technologies Inc., 2004, pp. 2-9.	(AS) 12/10/07
	A87	Michael HOPKIN, "A healthy heart in a single pill," Nature News Service, Macmillan Magazines Ltd, June 27, 2003, pp. 1 & 2.	
	A88	Alexis BORISY, et al., "Systematic discovery of multicomponent therapeutics," PNAS, Vol. 100, No. 9, June 24, 2003, pp. 7977-7982.	
/A.S./	A89	Drug Delivery Technology, 2005, vol. 5, no. 9, pp. 40-86.	

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Sheet 5 of 5				First Named Inventor Fred H. MILLER	Art Unit 1609
				Examiner Name Aradhana Sasan	Attorney Docket Number 027668-0108

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	A90	"Geminex - Dual Drugs, Dual Releases," Drug Delivery Technologies - Geminex - Penwest Pharmaceutical Co., 2003, 1 pg		
	A91	"Layer Capsules ENCAP DRUG DELIVERY," layer capsules co-administer solid liquid components, 2003, 1 PG.	N/A (AS)	12/10/07
/A.S./	A92	"Main Benefits of Liquid Fill ENCAP DRUG DELIVERY" liquid fill encapsulation beats tablet alternative, http://www.encapdrugdelivery.com/benefits.html , 2003, 1 PG.	N/A (AS)	12/10/07
	A93	"DuoCap Capsules™, ENCAP DRUG DELIVERY" liquid fill encapsulation preferable to tablet alternative, http://www.encapdrugdelivery.com/multi-component.html, 2003. PGS. 1 & 2.	N/A (AS)	12/10/07
	A94	"What does encap do?, ENCAP DRUG DELIVERY" pharmaceutical companies prefer liquid fill capsule solutions, http://www.encapdrugdelivery.com/, 2003, 1 PG.	N/A (AS)	12/10/07
	A95	"Ingestible Encapsulation," BioProgress Ingestible Encapsulation, http://www.bioprogress.com/ingestible.html, 2003 pp. 1-2.	N/A (AS)	12/10/07
/A.S./	A96	Scott HENSLEY, "Drug Makers 'Combos' Treat Two Disorders With One Pill," The Wall Street Journal, 2004, (Copyright © 2004, Dow Jones & Company, Inc.), pp. 1-3.		
/A.S./	A97	"FDA Approves Pfizer Medicine Caduet for the Treatment of Hypertension and High Cholesterol," FDA Approves Pfizer Medicine Caduet for the Treatment of Hypertension and High Cholesterol, http://www.medicalnewstoday.com/medicalnews.php?newsid=5666 , February 3, 2004, pp. 1-3.		

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